Gentamicin Injection BP

80mg / 2ml

GENTIME

Composition:

Each 2ml Contains:		
Gentamicin Sulphate BP		
Equivalent to Gentamicin		80mg
Methylparaben	BP	0.18% w/v
(As preservative)		
Propylparaben	BP	0.02% w/v
(As preservative)		
Water for Injection	BP	q.s.

Therapeutic indications:
Gentamicin is indicated in adolescents, children and adults for the following: The treatment of systemic infections due to susceptible bacteria, sepsis, urinary tract infections and severe chest infections.
Official local guidelines regarding the proper use of antibacterial agents should be considered.

Pediatric population:
The recommended daily dose in children and adolescents with normal renal function is 3-6 mg/kg body weight with one (preferred) to two single doses.
The daily dose in infants years the first month of life is 4.5-75 mg/kg body weight per day as one (preferred) to two single doses.
The daily dose in neonates is 4-7mg/kg of body weight per day. Due to the longer half-life, newborns receive the necessary daily dose in a single dose.

Method of administration:
Gentamicin is usually administered intramuscularly, but it can be given intravenously by slow intravenous injection over at least 3 minutes or short infusion if required. Gentamicin should not be given as a slow infusion or mixed with others. drugs before using.
Monitoring:
It is recommended to monitor the blood concentration of gentamicin, especially in the elderly, in newborns and in patients with renal failure. Samples are collected at the end of an interval dosage (minimum level). The trough levels should not exceed 2 µg/ml when administering gentamicin two times daily and 1µg / ml for a daily dose.
Long-term use should be avoided and, whenever possible, treatment should not exceed 7 days. Caution is recommended in significant obesity, as gentamicin is poorly distributed in tissue adipose. Dosage calculation should be based on an estimate of lean body weight. Serum levels should be carefully monitored and the dose possibly adjusted.

Contraindications:
Hypersensitivity to the active substance or to any of the excipients or to other aminoglycosides. Grave myasthenia.

Special warnings and precautions for use:
To avoid adverse reactions, continuous monitoring (before, during and after) of renal function is recommended. (serum creatinine, creatinine clearance), control of vestibule and cochlear function, as well as parameters liver and laboratory tests. When kidney function is affected by disease or old age, the frequency, but not the amount, of each dose should be reduced according to the degree of impairment. gentamicin it is excreted by simple glomerular filtration and the dose frequency can be predicted by evaluating the serum creatinine, blood creatinine or urea clearance rates and reduced frequency in conformity. Volume depletion or hypotension and liver disease have been reported as risk factors additional for nephrotoxicity.

In some patients with impaired renal function, there was a transient increase in blood-urea-nitrogen, which generally reverted to normal during or after the cessation of therapy. It is important to adjust the dose frequency according to the degree of kidney function. Ototoxicity was recorded after the use of gentamicin. Liver function or impaired hearing function, bacteremia and fever have been reported as factors that increase the risk of ototoxicity. The risk groups include patients with kidney failure, infants and possibly the elderly. Therefore, the renal, auditory and vestibular function should be monitored in these patients and serum levels determined. in order to avoid maximum concentrations above 10 mg/L and minimum concentrations above 2 mg/L to administer gentamicin twice daily and 1 mg/L trough concentration for one daily dose. as there evidence that the risk of ototoxicity and nephrotoxicity is related to the level of total exposure, duration of therapy should be as short as possible consistent with clinical recovery. Caution is needed in Parkinsonism and other conditions characterized by muscle weakness.

Fertility, pregnancy and breastfeeding Pregnancy:
Safety for use in pregnancy has not been established. Gentamicin crosses the placenta and there is a risk of ototoxicity (hearing or vestibular nerve disorders) in the fetus. Gentamicin should only be used when the severity of the mother's condition justifies the risk and use is considered essential by the physician. In these cases, the monitoring of serum gentamicin concentration is essential. Some animal studies have shown a teratogenic effect.

Breast-feeding:
Gentamicin is excreted in breast milk but is unlikely to be a risk to the child, except in presence of maternal renal failure as levels in breast milk increase considerably - breastfeeding should be avoided. In the absence of gastrointestinal inflammation, the amount of gentamicin ingested from milk is unlikely to result at significant blood levels in infants.

Storage:
Store below 30°C.

Keep the medicine out of the reach of children.

Presentation: Pack of 2ml x 10 Ampoules.

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